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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/541,191	10/11/95	KAYYEM J	A-62629/RFT

EXAMINER	
JONES, D	
ART UNIT	**PAPER NUMBER**
1211	9

12M1/0707

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DATE MAILED: 07/07/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/24/97.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 sheets

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

* U.S. GPO: 1996-409-290/40029

RESPONSE TO APPLICANT'S ARGUMENTS

1. Applicant's arguments (filed 4/24/97, Paper No. 8) with respect to claims 1-9, 14-15, 17, 19, and 22 have been considered but are moot in view of the new ground(s) of rejection.

DOUBLE PATENTING

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-4, 6-10, 12-13, 16, and 22 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8, 12, and 21-23 of copending Application No. 08/321,552. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

4. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 5, 11, 14-15, and 17-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-11, 24-27, and 35-38 of copending Application No. 08/321,552. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instantly claimed invention differ from those of 08/321,552 in that Applicant states that the contrast agent

is specifically a gamma, positron, optical, or fluorescence agent whereas the instant invention is not limited to specific techniques utilizing the contrast agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

103 REJECTION

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (Proc. Natl. Acad. Sci., USA, 1990, Vol. 87, pp. 3410-3414) in view of Kornguth et al (US Patent No. 5,230,883).

Applicant's invention is drawn to a cell specific delivery vehicle, a method of delivering a nucleic acid to a cell, and a method of delivering physiological agents to a cell wherein a delivery vehicle comprising: (1) a first polymer with a net negative or positive charge; (2) at least one of a second polymer with a net charge opposite to that of the first polymer; (3) at least one physiological agent attached to the first polymer, second polymer, or to a third polymer having a net charge opposite to that of the first polymer and complexed to it, is utilized. In addition,

Applicant has claims drawn to vehicles in which a first polymer has a net positive charge which includes hydrophobic residues to facilitate cellular uptake, complexed to a second polymer having a net negative charge.

Wagner et al discloses transferrin-polycation-conjugates useful as carriers for DNA uptake into cells. In particular, the nucleic acid delivery system involves conjugating the protein, transferrin to polycations that bind nucleic acids. The covalently linking of transferrin to the DNA protein, protamine, or to polylysines of various sizes occur through a disulfide linkage. In addition, the reference discloses: (1) the synthesis of the transferrin-polycation conjugates; (2) conjugation of transferrin with polylysine and protamine; (3) the formation of complexes between transferrin-polycation conjugates and DNA; and (4) the cell uptake and expression of luciferase gene resulting from the transferrin-polylysine and transferrin-protoamine conjugates mediating DNA uptake. However, Wagner et al fails to disclose the addition of a physiological agent such as a contrast agent or therapeutic agent.

Kornguth et al discloses methods of selectively localizing, imaging, and/or treating tumors wherein complexes containing polylysine, a linking agent bound to the polylysine, and an imaging agent or chemotherapeutic agent is utilized. In addition, Kornguth et al discloses specific examples wherein polylysine is coupled to a linking molecule, DTPA, and coupled to a metal ion, Gd, which is used for magnetic resonance imaging. Kornguth et al also discloses the following: (1) the polylysine can be use to deliver several nuclides or chemotherapeutic agents simultaneously because of the abundance of epsilon amino groups on the polymer and (2) the

preferred chelating agent for the polylysine complexes is DTPA; however, other chelating agent such as DOTA may be used (see entire document, especially, abstract; column 2-3, lines 57-68 and 1-50, respectively; column 6, lines 7-68; column 9, lines 10-59).

It would have been obvious to a person of ordinary skill in the art at the time of the invention to make the necessary modifications to the transferrin-polycation-DNA complexes disclosed by Wagner using the teachings of Kornguth et al; thus, generating a two polymer-cell targeting complex containing at least one physiological agent because Wagner discloses a highly efficient polylysine complex which, as disclosed by Kornguth et al, is commonly covalently coupled to an imaging agent or chemotherapeutic agent which is bound to a linking moiety and used for diagnostic or therapeutic imaging.

8. The prior art made of record and not specifically relied upon in any rejections cited above is either: (a) considered cumulative to the prior art that was cited in a rejection; (b) considered pertinent to applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application; or (c) was published after the applicant's filing or claimed priority date.

Note: The Wu et al reference (J. Biological Chemistry, Vol. 266, No. 22, pp. 14338-14342) in view of Kornguth et al (US Patent No. 5,230,883) is cumulative to the prior art cited in the above rejection.

9. Papers related to this application may be submitted to Group 1200 by facsimile transmission. Papers should be faxed to the Group 1200 fax machine at (703) 308-4556. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30; November 15, 1989.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dameron L. Jones whose telephone number is (703) 308-4640. Examiner Jones can generally be reached from Monday through Thursday, as well as on alternate Fridays, between 7:00 a.m. and 4:30 p.m. If the Examiner cannot be reached, questions may be addressed to her supervisor, John Kight, whose phone number is (703) 308-0204.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

DLJ
June 25, 1997

JOHN KIGHT
SUPERVISORY PATENT EXAMINER
GROUP 1200